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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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2292	7590	12/30/2003	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			GORDON, BRIAN R	
		ART UNIT	PAPER NUMBER	6
		1743		

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

)

Office Action Summary	Application No.	Applicant(s)	
	09/899,178	SENTOH, MASAYASU	
	Examiner	Art Unit	
	Brian R. Gordon	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 October 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-14 is/are pending in the application.
 4a) Of the above claim(s) 13-14 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,4,6,7 and 9-11 is/are rejected.
- 7) Claim(s) 3,5,8 and 12 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. Newly submitted claims 13-14 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 13 requires a first movable member supporting a first end of the specimen vessel and adapted to be movable by the drive source; Claim 1 does not require a first movable member supporting a first end of a specimen vessel.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 13-14 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments

2. Applicant's arguments filed October 7, 2003 have been fully considered but they are not persuasive. Applicant asserts that prior art does not disclose a single drive source and the third member of claim. The examiner respectfully disagrees and asserts that the combination of references meet the required positively claimed limitations of the claim. Wilks discloses an aspiration and suction apparatus that comprises two movable elements for sandwiching and holding a vial to be accessible by the stationary needle. Stettler on the other hand discloses a device in which a stationary vessel is accessed by a movable needle. As previously stated it would have been obvious to one of ordinary skill in the art to modify the device of Wilks by incorporating the movable motor driven needle

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of Stettler to allow for automation of accessing the vessels without the use of manual force.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 1, 3, 8, and 11 the specimen vessel should be positively recited as an element of the invention for the drive source and movement of the members are claimed in a manner relevant to the unclaimed vessel. It also appears that applicant is attempting to claim the "single drive source" in a manner similar to means plus function language in which applicant intends for the intended action or ability of the drive source be considered as structural limitations of the element. It is suggested that in order for the intended action of the drive source to be considered as limitations claim 1 be amended to one of the following: "a single drive source provided on the third member [for]; said single drive source adapted to [for] perform[ing]; or said single drive source is capable of performing

It also appears as if claims 3 and 8 should be amended to one of the following phrases: ...,wherein the drive source is adapted to reduce or capable of reducing the distance

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Claims 9-11 fail to further structurally limit the apparatus of claim. Claim 9 is directed to a method step in which the device is used to draw blood. The claim is not directed to an additional structure limitation.

Claims 10 and 11 are directed to a "hematology analyzer" which is comprised of the device of claim 1 and other elements. It is unclear how the device is referred to as a hematology analyzer when no analyzing structure is claimed in the claims. In order for the claimed device to be considered an analyzer an analyzing structure should be included in the elements.

Claims 10 and 11 contain numerous "for" phrases that express the intended use of elements however these phrases are not considered as further limiting the structure of the device. Claim 10 claims "a conveyor for transferring racks....." The claim expresses intended use of the conveyor in reference to unclaimed elements (racks and plurality of specimen vessels). These elements are not positively claimed as elements of the invention and such cannot be considered as limitations in relation to the conveyor. As such the claim is interpreted as a conjunction of the conveyor and the apparatus of claim 1. Furthermore, there is no structural relationship provided for the conveyor and the device of claim 1. It would be unclear for one of ordinary skill in the art to determine how the elements are structurally arranged in relation to one another.

Claim 11 also claims elements in relationship to unclaimed elements (storing racks and plurality of specimen vessels). It is also unclear how the device of claim 1 is structurally related to the elements claimed in claim 11

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-2, 4, 6-7, 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilks US 5,578,495 in view of Stettler US 5,240,679 or Preston et al. US 6,274,087.

Wilks disclosure is related to automated fluid injection devices, particularly automated needle syringes, have gained wide acceptance by industry and by the scientific and medical communities. This is because these devices are generally capable of dispensing very small, accurately measured quantities of fluid specimens on the order of a few microliters, generally a fractional part of a microliter. In the operation of these devices many samples are prepared in advance, the specimens placed in vials, the vials placed in a magazine, or tray and the samples run with minimal operating labor. Typically, e.g., septum covered bottles, or vials charged with a fluid specimen, are

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transported in seriatim via a magazine to a station adjacent a probe assembly, a needle of the probe assembly is projected through the septum of a vial and employed as a conduit to convey a portion of the fluid specimen to the barrel of the syringe. The circuit through which the specimen is conducted, and barrel and needle of the syringe are cleaned, purged and a quantity of the fluid specimen is measured out and injected via the needle end of the syringe into the inlet of an analytical instrument, e.g., a G.C. or mass spectrometer.

The solids preparation and extraction sub-assembly 200, as shown by any of FIGS. 1-4, includes generally an electrical heater, or oven 210, and an elevator assembly 220 inclusive of an upper carriage section 222₂ and a lower carriage section 222.sub.1. It further includes an elevator motor 221 for raising and lowering the elevator assembly 220, and a stir motor 223 for inductive rotation of the magnetic stir bar 258 contained within vial 250. The electric oven 210, which is secured in place in fixed position upon a generally upright frame structure, housing and tower assembly, below the plate 211, is constituted of an electric heating element-containing wall, to which current is supplied via electrical leads (not shown) surrounding an open space within which the elevator carriage 222, supported upon a generally upright frame structure, housing and tower assembly, and carrying a vial, or bottle 250 within which a solution can be added to contact a solid or semi-solids material, can be raised, housed and heated. The electrical heating element 213, it will be observed, is located between side walls 214₁, 214.sub.2 of the heater, and on one side thereof is provided insulation 215. Within the plate 211 is provided an opening or aperture through which the pair of

concentrically mounted tubular needles 212 is projected, and rigidly retained in fixed vertical position. The inner needle 212₁ is connected via a valved line 212.sub.1A and line 212_{1C} (with valved line 212_{1B} closed) to a supply source through which a liquid solvent, suitably a preheated liquid solvent if desired, can be introduced (FIG. 3). Alternatively, a gas can be supplied to the inner needle 212₁ via lines 212_{1B}, with 212_{1C} (with line 212_{1A} closed; see FIG. 4). The outer needle 212₂, with the inner needle 212.sub.1, provides an annulus through which gas from the headspace above the level of the liquid in bottle 250 can be passed via outlet line 212_{2A} (FIG. 4). The elevator assembly 220, constituted of a carriage 222 provided with lower and upper elevator sections 222₁ (first member) 222₂ (second member) are slidably mounted in a vertical groove (not shown) of the housing or tower assembly for upward and downward movement within the support structure, or tower. The elevator carriage 222 can be reciprocated by the elevator motor 221, the shaft (not shown) of which is geared thereto by a mechanism (not shown).

Wilks does not disclose a third moveable member and an elastic compressible spacer between the second and third members.

Preston et al. disclose an invention that relates to a diagnostic medical device, and in particular to a blood cell analyzer (hematology) which by manual or automatic operation withdraws and analyzes a minimal amount of blood that is stored in open or sealed vials. The analyzer includes a manually operated self cleaning sampling device for open vials and an automated self cleaning sampling device for sealed vials fitted with a pierceable cap.

FIG. 2 shows a preferred embodiment of the variable size vial holder and cap piercer 11. This apparatus comprises a frame 12, an adjustable holder 14, a top plate 16, a cup 18, an extendable and retractable needle 20, and a driver 22 for extending and retracting the needle 20. A multi-lobe cam 22a with associated position switches 24 is used to detect needle position. In addition, a safety switch 24a is used for interlocking the driver with the holder 14 so that the driver 22 cannot extend the needle 20 when a vial 23 is not fully engaged in and held by the holder 14 (third member).

In the preferred embodiment, the holder 14 is an over center spring (elastic member) loaded mechanism of the configuration shown in FIG. 4. The holder 14 includes a U-shaped clamp 32 adjustably mounted to the frame 12 and an oblong-shaped tongue 34 mounted between two arms 33 of the clamp 32. The tongue 34 is retained in the clamp 32 by a pin 36 which extends across the width of the clamp 32. The tongue 34 has a beveled surface 35 and pivots about the axis of the pin 36.

Stettler discloses and apparatus for the automatic introduction of a pipetting insert through the stopper of a sample vessel sealed by the stopper and containing a sample.

The apparatus shown in FIG. 1 comprises, inter alia, an entry device 51 on a platform 46, positioned on the base of the apparatus under the press-in means 55 (third member) to receive and position the sample vessel 13, a feed means 52 which takes individual pipetting inserts 11 successively to a delivery station 53, and a press-in means 55 movable by a drive means 54 and containing a plunger 41 by means of which

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a pipetting insert 11 is taken from the delivery station 53 and introduced into the stopper 14 of a sample vessel 13 contained in the entry device 51.

The press-in means 55 and hence the plunger 41 are moved downwards by drive-means 54 to an extent such that the pipetting insert 11 is pressed as deeply as possible into the stopper 14 and assumes the position shown in FIG. 3. The maximum tension of the spring (elastic member) 43 is achieved in this position and the top end of the plunger 41 is situated directly adjacent the electromagnet 42. At this time voltage sufficient to hold the plunger 41 in the press-in means 55 in the position shown in FIG. 3 against the force exerted by the tensioned spring 43 is applied to the electro-magnet 42 by means of suitable leads (not shown). Immediately thereafter the press-in means 55 is raised by means of drive-means 54 so that the plunger 41 is withdrawn from the pipetting insert 11, which is left in the stopper 14. As shown in FIG. 4, the plunger 41 remains held by the electromagnet 42.

To detect the position of a pipetting insert 11 inserted in a stopper 14, the press-in means 55 is moved down from the position shown in FIG. 1 by means of drive-in means 54 and introduced into the cavity of the pipetting insert 11. During this movement the sensor 57 detects the time at which an upward movement of the top part of the plunger 41 starts. If this upward movement starts before the press-in means 55 has covered a predetermined distance, the level-sensing means detects and signals that the pipetting insert 11 has not been inserted sufficiently deeply in the stopper 14. Repetition of the pressing-in operation and impact is then initiated by an appropriate output signal from the level sensing means.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Wilks to include an automated reciprocating moveable needle means and spring in order to allow for adequate pressure to insert and remove the needle from vessels comprising seals manufactured from various materials.

Allowable Subject Matter

6. Claims 3, 5, 8, and 12 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
7. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach nor fairly suggest a device that comprises a drive source that comprises an air cylinder having a piston rod, the air cylinder being provided on the third member and a distal end of the piston rod being connected to the first member and a second member the includes a washing bath for washing the suction needle.

Conclusion

In an attempt to expedite the allowance of claims 1-8 and 11-12, the examiner made a called to Terrell C. Birch to propose the examiner's amendment that included amending claims 1, 3, and 8 and canceling claims 9-10 and 13-14. Carolyn Baumgardner 41,345 responded on October 27, 2003 with applicant's refusal to the proposed amendment.

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8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


Jill Warden
Supervisory Patent Examiner
Technology Center 1700